



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

June 2, 2000

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

KAN #2000-019

Ms. Grace Silva, Owner
Ms. Jean N. Miller, Owner
Spanish Gardens Food Mfg., Inc.
2301 Metropolitan Avenue
Kansas City, KS 66106

Dear Ms. Silva and Ms. Miller:

An inspection of your food manufacturing facility on April 24 through May 4, 2000 conducted by an Investigator representing the Federal Food and Drug Administration (FDA) revealed significant insanitary conditions and insect infested raw and finished food products. Food that has been contaminated by the conditions within a food manufacturing facility is adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug and Cosmetic Act (the Act). Our Investigator also documented insanitary conditions that may cause your food products to become adulterated within the meaning of Section 402(a)(4) of the Act.

At the conclusion of the inspection Form FDA483, Notice of Inspectional Observations, detailing some but not all of the insanitary conditions and product contamination in your facility was discussed with you. Some of the conditions noted are:

1. Raw materials stored in your plant were contaminated with live and dead insects. Adulterated product included blue corn, white corn, flour, wheat flour, dry whey, dry powder milk and sodium bicarbonate.
2. No protective screens on overhead outside air vents.
3. Ceilings deteriorated to the point where insulation is exposed and falling into production equipment.
4. Holes in the roof adjacent to the production area exposing the facility to open air.
5. Poor lighting and lights throughout the facility without protective shields.
6. Food production equipment used in the manufacturing operations were not properly cleaned or maintained. This included crusted over ingredient residues found in mixing vats, baggers, fillers, dough rollers, tables and pans.

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7. Poor employee practices such as ungloved employees working in the production area with open wounds on their hands. This is just one of many objectionable employee practices pointed out at the conclusion of the inspection.

We also collected physical samples for analysis from your facility. Our analysis reveals insect infestation in both raw materials and finished products. The samples appear to indicate a direct route of contamination from the adulterated raw materials to the adulterated finished products.

The listed observations and results are just selected examples depicting the out of control conditions within your food manufacturing facility. Food products manufactured, stored and distributed under the conditions in your facility may cause the products to be adulterated under the Act. Failure to correct, fully and permanently, all unacceptable conditions in your food manufacturing operations may result in the FDA taking actions including but not limited to seizure and/or injunction.

Please respond within fifteen (15) working days after receipt of this letter with complete descriptions and documentation of the corrective actions your firm will take to bring your facility into full compliance with all regulatory requirements and to prevent future distribution of adulterated foods. In your corrective actions please indicate the date each correction will be completed.

Your response should be directed to Ralph J. Gray or John W. Thorsky at the above address.

Sincerely,



Ann M. Adams
Acting District Director
Kansas City District Office

Cc: Launa Osbourn, Food Protection Investigator
Kansas Department of Health and Environment
109 SW 9th, Suite 604
Topeka, KS 66612-1290